DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-64

July 7, 2000

Joseph A. Letson, President
Summerland Seafood, Inc.
P.O. Box 1149
Mile Marker #25
Summerland Key, FL 33042

Dear Mr. Letson:

We inspected your firm, located at Mile Marker #25, Summerland Key, FL on September 2-3, 1999 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, most of which were previously brought to your attention, cause your fresh fish and cooked stone crab claws to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have HACCP plans that list all necessary critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for scombrotoxin-forming species of fish (pelagics) does not list a critical control point at finished product cooler storage to control the food safety hazard of histamine and your firm's HACCP plan for cooked stone crab claws does not list critical control points at pre-grading refrigerated storage and finished product cooler storage to control the food safety hazard of pathogen growth and toxin formation. Additionally, your hazard analysis and HACCP plan for stone crab claws addresses the cook as a critical control point designed to destroy pathogens, although both identify the intended use as "cook and serve." The hazard analysis and HACCP plan should identify the intended use as a cooked ready-to-eat product.

You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrotoxin-forming species of fish (pelagics) lists critical limits of visual and sensory attributes and a temperature of 45° F or less at the receiving critical control point that are not adequate to control the histamine hazard. Specifically:

a) Your maximum acceptable internal temperature of the fish is too high. To protect from histamine development, fish received directly from the vessels 12 or more hours after death should have internal temperatures at 50° F or below and fish received 24 or more hours after death should have internal temperatures at 40° F or below. Your critical limit at receiving should specify **internal** temperatures of the fish and specify the measurement criteria in degrees Fahrenheit or Centigrade.

b) You list no requirement to check for adequacy of ice on product, or to obtain records of temperature maintenance during transit of product received by truck;

c) Your approach to providing vessel instructions to your suppliers through the Declaration of Fishing Practices is noted. However, to ensure and document that the fish were handled appropriately to prevent histamine development, your firm should include collection of applicable vessel records. These could include method of capture, date and time of landing, air and water temperatures at the time of landing, estimated time of death of the fish, method of cooling and temperature of cooling media, and date and time cooling began. Alternatively, you could conduct histamine analysis for each lot received by vessel; and

d) Your criteria for visual appearance and sensory evaluation do not provide clearly defined limits or parameters for decision making.

You must have HACCP plans that list monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for scombrotoxin-forming species of fish (pelagics) lists monitoring procedures at the Receiving critical control point that are not adequate to control the histamine hazard, as it fails to include monitoring of the internal temperature of the fish received directly from fishing vessels and monitoring for the adequacy of ice or transit records for fish received by truck. The monitoring procedures should specify how many fish are to be examined from each lot, or they should specify 100% inspection. Also, your HACCP plan for cooked stone crab claws lists monitoring procedures at the cooking and cooling critical control points that are not adequate to control the pathogen growth and toxin formation hazard, as it describes a procedure for monitoring the cooking and cooling time with a timer, instead of the beginning and ending times. In addition, your HACCP plan for cooked stone crab claws does not account for temperature monitoring at the cooking control point. If the cook integrity is based on retention of a full boil for 8 minutes, then the boiling must be monitored continuously with a temperature recording device or by visual observation and documentation of boiling during the entire cook cycle.

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Receiving critical control point to control the histamine hazard listed in your HACCP plan for scombrotoxin-forming species of fish (pelagics).

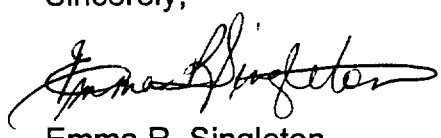
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as revised HACCP plans and revised monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,



Emma R. Singleton
Director, Florida District